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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,091	05/13/2005	Kevin Russel Oliver	T1590YP	2027

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/535,091	OLIVER ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-54* is/are pending in the application.

4a) Of the above claim(s) *24-28,36-42 and 44-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,29-35 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 23 to 54 are pending in the instant application.

Election/Restrictions

Claims 44 to 48 and 50 to 54, as well as claims 23 to 43 and 48 in so far as they related to a method of treating that does not require "a compound which modulates the activity of a VR2 polypeptide", are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected invention**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 April of 2006. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 24 to 28, 36 to 42 and 44 to 54, as well as claims 23 and 46 in so far as they related to a method of treating other than a circadian rhythm disorder, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected species**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 April of 2006. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

) Claims 23 to 54 stand objected to as reciting an improper Markush Group for those reasons of record in section 2 of the office action mailed 31 March of 2006.

Correction is required.

Drawings

The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 1 of the instant application, for example, is presented on three separate panels. The three sheets of drawings which are labeled " Figure 1" in the instant specification should be renumbered "Figures 1A, 1B, and 1C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 29 to 35 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. The instant claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and n in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for the treatment of circadian rhythm disorders by administering an effective amount of a compound which modulates the activity of a VR2 polypeptide to a patient in need of such treatment. Neither the claimed method nor the required compound are adequately described in the instant specification.

The claimed method requires a compound which modulates the activity of a VR2 polypeptide. The instant specification, however, fails to identify even a single actual compound having the required activity. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The claimed subject matter is not enabled because the specification does not describe the genus of compounds encompassed by the limitation "a compound which modulates the activity of a VR2 polypeptide" by structure, formula, chemical name, or physical properties" or a single example thereof.

The inadequacy of the description provided by the instant specification is illustrated by the fact that a proper search for the claimed subject matter can not be performed. If the instant specification or the art of record actually identified a representative number of compounds that modulate the activity of a VR2 polypeptide by structure, formula or chemical name, a search of the art for any association between such compounds and the treatment of circadian rhythm disorders could be conducted. The fact that those compounds modulate a VR2 polypeptide would be irrelavent to that search because the discovery of an inherent property of a prior art process can not serve as a basis for patenting that process. See M.P.E.P. 2112.02 and *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.). However, because the instant specification does not adequately describe the required compound, one can not determine if the instant claims

inherently encompass a process that was in use before the making of the instant invention.

The instant claims are not enabled because one of ordinary skill has no reasonable expectation that the administration of a compound that modulates the activity of a VR2 polypeptide will have any effect whatever on a circadian rhythm disorder. The instant specification provides neither working examples, sound scientific reasoning or evidence that the administration of a compound that modulates the activity of a VR2 polypeptide has any effect whatever of the circadian rhythm of a mammal. At best, Applicant has shown that VR2 polypeptide is expressed in portions of primate brain associated with a plurality of functions, including regulating circadian rhythm. However, one of ordinary skill in the art of neurobiology was well aware, before the making of the instant invention, that any viable mammalian cell normally expresses over five thousand different proteins. Therefore, that artisan would not reasonably believe that each and every protein expressed in a particular tissue regulates each and every function known to be associated with that tissue. Therefore, the assertion that a compound that modulates VR2 activity can be employed to treat circadian rhythm disorders would not be found believable by one of ordinary skill in view of the evidence of record.

Further, to practice the claimed method would require knowledge of the route, duration and quantity of administration of the recited VR2 modulating compound to a subject and this information is not provided by the instant specification. The guidance provided on pages 17 and 18 of the instant specification is notable for its lack of

specificity and clearly fails to supply the guidance that would be needed by a routine practitioner. The instant specification has also failed to disclose how these parameters are to be determined, how a similar method was practiced in the art with a different agent or to provide even a single working example, prophetic or actual, of the claimed method. In the absence of this guidance a practitioner would have to resort to a substantial amount of undue experimentation involving systematic variation of the amount and duration of administration of a VR2 modulating compound of the instant invention and in determining a suitable route of administration.

The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph". A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by

asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making several substantial inventive contributions.

The prior art made of record and considered pertinent to applicant's disclosure

The Watanabe et al. (J. Biol. Cham. 277(16):13569-13577, 2002), Caterina et al. (NATURE 398 :436-441, 01 Apr. 1999) and Kanzaki et al. (NATURE CELL BIOLOGY 1:165-170, Jul. 1999) publications are being cited because they appear to best represent the state of the art relative to VR2 agonists and antagonist. The first paragraph of the Watanabe et al. publication, which is contemporary with the filing of the instant application, states that the VR2 protein of the instant invention, also known as VRL-1, "is constitutively activated by growth factors or by noxious heat". Watanabe et al. cites Caterina et al. as the source of the relationship between VR2 and growth factors. Caterina et al. discloses that growth factors do not act directly upon VR2, also known as GRC, but stimulate cells to translocate VR2 from intracellular pools to the plasma membrane upon exposure to a specific growth factor. Figure 2 of the Kanzaki et al. publication shows that VR2 is directly activated by heat, but not by any of the compounds tested. None of these references identify any compound that is known to act directly upon VR2 as either an agonist or an antagonist.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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